TECHNOLOGIES INC.

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Dockets Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane,
Rm. 1061
Rockville MD 20852

Dear Sir or Madam,

Indico Technologies Inc. is pleased to be able to provide comments for the ANPR for the labeling of irradiated foods. We manufacture radiation sensitive indicator labels and so are keenly interested in regulations that will improve the adoption of food irradiation.

Our products provide unequivocal verification that a product was irradiated. Our technology is flexible and can be part of any label design. We can incorporate radiation sensitive label technology into any design, from individual labels to case sealing tape. It can be part of a symbol, wording, a color marker, or irradiation wording. Our labels can be used for consumer level information, or can be used at wholesale level, on packing boxes or on shipping documents placed inside shipping boxes.

Unlike many other radiation sensitive labels, our product functions well in the food irradiation dose range; it is not sensitive to environmental conditions such as sunlight, temperature, long term storage, etc. With our product, food processing workers from quality assurance managers to warehouse staff will have immediate, reliable, visual confirmation that a product has, or has not, been irradiated.

The success of our food label product line is dependent on the sensible development and use of food irradiation. Indico is a technology company, with broad health care interests. New technologies, such as food irradiation and our radiation sensitive label, make important contributions towards improved food safety and public health. The development of a food irradiation market for our labels has been slowed by long waits for regulatory decisions, and by labeling requirements that disadvantage irradiation compared to competitive treatments.

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Indico Comments

Voluntary labeling

We favor voluntary labeling of irradiated foods because removing current label requirements will encourage the use of food irradiation. We are confident that the food industry will need and adopt our labels, but first they must start using irradiation as a technology to make food safer from bacterial contamination, to control pests, and for other technical benefits.

Any decision for further consumer labeling should be marketing decisions. Some companies may want to provide their customers with more information about the purpose of irradiation or the benefits it offers. Other companies may want to use our labels on their products to give the consumer the visual assurance their product was treated. This marketing approach will not be possible until consumer familiarity and acceptance with irradiated foods improves. That will not happen until there are more irradiated foods being sold, and consumer education is improved.

Voluntary labeling will encourage food companies to irradiate their products to improve food safety, to replace chemical treatments (for pest control for example), or for other technical benefits. The consumer will benefit from the use of irradiation when food safety and food processing is improved. Food companies can then indicate the use of irradiation in a way that is compatible with their marketing strategies.

Allowing companies to use irradiation and work labeling into their marketing strategies will encourage companies to inform consumers in a more meaningful way than the label. Research on consumer attitudes towards irradiated foods has shown that several methods are useful, but that the label is not very useful as a consumer education tool. Pamphlets, discussions, videos and other consumer education materials and methods have been researched and encourage consumers to understand and trust irradiation (Bruhn et al, 1986; Hashim et al, 1996; Pohlman et al, 1994). One early study conducted to assess consumer attitudes towards label statements used label statements with strongly positive benefit statements. These statements did positively affect consumer attitudes (Schutz et al, 1989).

Hashim et al, (1995) simulated grocery store marketing of irradiated chicken, studying the effect of label and educational materials on consumer purchasing behavior. They determined the label previously designed by a consumer focus group had no effect on the participant's decision to purchase irradiated poultry. On the other hand, an informative slide program was much more effective in positively affecting sales. So, we conclude the label is a relatively ineffective information tool for informing consumers about irradiated foods.

Research indicates that even a small amount of information is remembered by consumers and improves consumer attitudes. Lusk and co-workers (1999) found that very scant information provided 2-3 weeks earlier also had a positive effect on consumer attitudes towards food irradiation. Bruhn and coworkers (1986) and Resurreccion and coworkers (1996) working with consumer focus groups found consumers, when presented with information about irradiation were willing to buy irradiated foods.

Radiation sensitive label technology should be specified in HACCP plans

When foods are labeled in one location and shipped to another location for irradiation, radiation sensitive labels can ensure food company QA managers and food inspectors that the food has (or has not) been irradiated as planned. Since food companies may choose to irradiate products at a remote location, after freezing, or when labeling and irradiation processing takes place in a different section of a facility, radiation sensitive labeling can simply prevent confusion, and misrepresentation.

Our technology is flexible and can be part of any label design. We can incorporate radiation sensitive label technology into any design, from individual labels to case sealing tape. It can be part of a symbol, wording, a color marker, or irradiation wording. Our labels can be used for consumer level information, or can be used at wholesale level, on packing boxes or on shipping documents placed inside shipping boxes.

Beneficial labeling

If labeling is required, unobtrusive wording that indicates the benefit, and will not be viewed as a warning or disrupt food processing marketing efforts must be chosen. As FDA noted in the ANPR, legislators when approving the FDA Modernization and Accountability Act of 1997, indicated that the labeling chosen for irradiated foods must not be viewed as a warning. Words such as 'cold pasteurized', 'electronic pasteurization', 'treated to improve food safety', 'pests controlled without chemicals' or other words should be chosen. (With Indico's technology, these words can be designed to change color when the food has been irradiated.)

Currently, the words 'irradiated', or 'treated by irradiation' are not understood by consumers and the wording discourages food processors from using irradiation. Consumers and some members of the food industry incorrectly view these words as a warning, instead of indicating a safer food. The fact that consumers and some food industry members do not understand food irradiation, and are frightened by the word 'irradiation' was recently highlighted in a news report from the San-Antonio Express-News (Pfister, May, 8, 1999) Margaret Wittenberg, vice president of government and public affairs of Austin-based

Whole Foods Market was quoted. She remembers consumers being "flabbergasted" by the notion of irradiation, adding, "Our customers really try to find out about their food. How it's treated, grown, prepared and manufactured is very important to them. Most of them want to minimize anything that's too overly high-tech."

Improving food safety must be the first priority

Using irradiation could help food companies eliminate the senseless continuing cases of food borne illness and deaths from contaminated food (and the huge waste of food that could be prevented by irradiation). A regulatory decision on the labeling of irradiated foods must first consider the impact the required labeling will have on the adoption and use of irradiation. If the required labeling will be a detriment to the use of irradiation, then FDA should not require that irradiated foods be labeled, or the label requirement should be very unobtrusive and very positive.

Consumers are very concerned about food safety; when continuing reports of thousands of cases of illness and deaths from food-borne illness are reviewed, it is clear their concern is justified. Yet, this consumer concern, and the resulting impact on the credibility of the food industry and government, is not being considered by FDA. FDA might think that consumers are concerned about food irradiation, but research into consumer attitudes indicates consumers are less concerned about food irradiation than they are about food safety.

Focus groups on consumer attitudes towards irradiated poultry conducted by University of Georgia researchers revealed that some consumers have been made ill by poultry or were concerned about the safety of poultry. They mentioned mishandling by consumer cooks, the use of growth promoting hormones, the slaughtering process, unsanitary processing conditions and USDA inspection standards as concerns. These consumers who could all be characterized as heavy poultry consumers, said the most important benefit of irradiation was that it killed bacteria (mentioning Salmonella in particular) and that it extended shelf life (Hashim et al, 1996). The consumers in these focus groups predicted that irradiated poultry products would someday be as common as pasteurized milk. We hope so, but it will not happen unless label requirements do not inhibit the use of the technology.

Food contaminated with food-borne pathogens is not only unsafe, but illegal under the Federal Food, Drugs and Cosmetics Act. We can not improve food safety unless we give the food industry the arsenal it needs to combat the problem. We need a regulatory focus that demands safer food, and encourages the use of technologies to produce it.

Irradiation was ranked lowest out of 8 food safety concerns about meat among consumers in a recent Food Technology report. In that study, consumers ranked bacteria and spoilage as the highest food safety concerns. Concern about irradiation was significantly lower (in t-test analysis) than for all the other factors at the 1% significance level, a finding the researchers noted was consistent with the findings from many other studies (Lusk, Fox and McIlvain, 1999).

For example, earlier work by University of Georgia workers in a larger consumer study found a similar ranking of concerns. Over 400 participants ranked concern about food safety issues in 1994. Pesticide residues, bacteria, animal drug residues and growth hormones all ranked as higher concerns among participating consumers than did irradiation which was at the same level of concern as naturally occurring toxins (Resurreccion et al, 1995). We note that of the concerns mentioned by the consumers in this study, labeling is required only for irradiation.

Bruhn et al (1986) also noted that consumers showed a higher level of concern for food preservatives and sprays and chemicals than they did for irradiation. In their work, conventional consumers became even less concerned about irradiation after reading an information pamphlet, but alternative consumers became slightly more concerned. This result is further indication that labeling might increase food safety risks by mistakenly leading consumers away from irradiated foods. More recently Bruhn explained that it is not unusual for consumers to express some concern about a new technology. She noted that many consumers express concern about technologies generally recognized as safe (Bruhn, 1995)

Lack of consumer concern about irradiated foods is demonstrated by the continuing strong sales of irradiated Hawaiian produce in over one hundred stores in several states over several years. Hundreds of commercial scale shipments of Hawaiian produce have been irradiated in Illinois, first are part of USDA assessment of the control of quarantine pests and then as regular commercial practice following the approval of irradiation as a quarantine treatment for fruit fly.

University of Georgia researchers assessed consumer attitudes toward perceived 'need' for the irradiation processing. The irradiation of pork, poultry, seafood and beef was considered to be very necessary by 32-44% of the consumers studied, and only 12% of consumers considered the irradiation of produce to be necessary. They concluded the market potential for irradiated muscle foods would far exceed that of produce (Resurreccion, 1995)

We understand FDA faced a similar decision when deciding whether to require labeling of foods developed from biotechnology techniques. FDA decided not to require labeling (except in those rare instances when a allergen potential exists), because biotech foods are not much different than similar foods, the

labeling would have been costly, would have been a detriment to the development and utilization of biotech foods, and the labeling of biotech ingredients would have been unworkable.

Since the issues with biotech and irradiated foods are very similar, we do not understand why FDA has taken a different position with irradiated foods, especially when the result of required labeling is continued food safety risks. Satisfying the demand of consumer activist groups who want to ensure irradiated foods are not sold, is not a good reason to require labeling. Consumer groups have demanded the labeling of biotech foods too, and FDA decided against it.

FSIS labeling regulations must conform with FDA

In its recent Proposed Rule on the irradiation of meat, FSIS proposed label requirements that are more stringent than FDA's current requirements, and also proposed ingredient labeling. The food industry will not have the confidence it needs to adopt food irradiation if another branch of government can require more stringent label requirements. FDA should inform FSIS that its proposal requiring irradiation wording to be contiguous with the product name is not in keeping with the FDAMA, and that ingredient labeling is not allowed under the Federal Food Drug and Cosmetic Act. FSIS labeling regulations must conform with FDA.

Indico and other label manufacturers will also need to know that label requirements are consistent between government departments. We are currently developing radiation sensitive labels for a wide range of food and research applications. We hope to keep the costs of our labels very reasonable to encourage the food industry to use them. If, however, we have to develop a very wide range of labels because of differences in requirements between departments and for different foods (depending on who is inspecting them), costs will increase, and our potential business will decrease!

The labeling of ingredients, in particular, is unworkable. Food processors source ingredients from many suppliers; the annoyance and cost of having to label some ingredients and not others as irradiated will just force food processors to source unirradiated, and therefore potentially less safe food ingredients. The requirement to label irradiated ingredients then forces the preparation and use of two labels for the same processed food. This problem alone could be enough to stifle the use of irradiation for ingredients. As label manufacturers we point out that it would be unworkable and probably technically impossible to manufacture a radiation sensitive label for an irradiated ingredient that is a component in a further processed food that is not irradiated.

21 CFR Part 179.26 (c)(2) states that "The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated." In its discussion of the labeling of irradiated ingredients in its first Final Rule for irradiation (Federal Register, April 18, 1986, page 13389), FDA notes "As stated earlier, FDA believes that the irradiation of a food is a material fact that must be disclosed. The agency recognizes, however, that the irradiation of one ingredient in a multiple ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell or taste the same as fresh or unprocessed food or have the same holding qualities. Therefore, FDA advises that the retail labeling requirement applies only to food that has been irradiated when the food has been sold as such (first generation food) not to food that contains an irradiated ingredient (second generation food) but has not itself been irradiated." We call on FDA to insist FSIS conforms to FDA regulation in the matter of ingredient labeling.

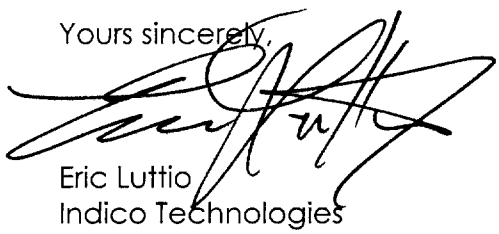
We see potential for misleading the public if irradiated ingredients are labeled in a mixed food. Eventually, consumers will understand a food safety benefit when meats or poultry are irradiated. Yet, when an irradiated ingredient is mixed with other foods, the microbiological safety and quality of the finished food is dependent on the performance and cleanliness of all the other ingredients and the processing, handling and storage of the finished food. A consumer, seeing the irradiation term used in labeling of the final food, may place a much higher level of trust in the safety of the food than is warranted.

Summary

In summary, we are concerned that FDA's current label requirements, and FSIS's proposed label requirement for irradiated meats are and will be a detriment to the use of irradiation. As a result consumers will continue to be placed at risk of food-borne illness, and our market for radiation sensitive indicator labels will not develop as it should. We call on FDA to make food safety its first priority and remove label requirements that deter the use of food irradiation.

We would be pleased to provide additional information on our products to FDA. Especially since our radiation sensitive label indicators can indicate the range of dose received by the product, unlike other labels on the market, our product might interest inspection officials. If additional information is needed, please contact us.

Yours sincerely,



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